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REMARKS

Reconsideration of the Final Office Action mailed May 21, 2003, (hereinafter "instant Office Action") and withdrawal of the rejection of claims 16-26 and 36, are respectfully requested.

In the instant Office Action, claims 16-26 and 36-38 are listed as pending, claims 37 and 38 are listed as allowed and claims 16-26 and 36 are listed as rejected.

Applicants thank the Examiner for the telephone interview conducted on January 20, 2004.

In the Final Office Action mailed May 21, 2003, the Examiner has rejected claims 16-26 and 36 under 35 U.S.C. §112, first paragraph, alleging that the application as originally filed did not provide adequate written description to support the proviso inserted by Applicants in the Reply mailed November 26, 2001. During the January 20, 2004 telephone interview, the Examiner indicated that the proviso was objectionable because it excised a genus of compounds rather than specific prior art compounds. The Examiner suggested replacing the earlier provisos excluding a subgenus with amendments so that species are excised. Applicants have made the suggested changes to the proviso clause. Thus, Applicants address below each rejection under 35 U.S.C. §102(b) as cited in the Office Action mailed May 24, 2001.

The Examiner has rejected claims 16 and 36 under 35 U.S.C. §102(b), as allegedly being anticipated by Varano et al., Chem Abstract 131: 44782. The Examiner alleges that the instantly claimed compounds read on the reference compound. Applicants respectfully traverse this rejection.

With respect to the Examiner's allegation that claims 16 and 36 are anticipated by Varano et al., the genres disclosed by compounds I and II and RN 227012-79-5, RN 227012-80-8, RN 227-12-81-9 and RN 227012-82-0 in Varano et al. are all substituted by chlorine at the 6- and 8- position of the benzothiazine ring, whereas Applicants' compound is unsubstituted at these positions. Varano et al. does not teach or suggest that the 6- and 8- position be unsubstituted. Additionally compound I in Varano et al. does not have a substituted methylene group at the 2- position of the benzothiazine ring. Compounds 5 and 7 of Varano et al. do not anticipate Applicants' compound because they are all monocyclic compounds, whereas Applicants' compound is a bicyclic heterocycle. Compound 6 of Varano et al. does not anticipate claim 16

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because it is composed of a six member ring fused to a five member ring, whereas the compounds of claim 16 are composed of two six-membered rings fused together. The genuses disclosed by compounds 8, 9, 10, and 11 of Varano et al. also do not anticipate claim 16 because they do not contain a substituted methylene group at the 2-position of the benzothiazine ring as does Applicants' compound. Therefore, Varano et al. does not anticipate Applicants' claims 16 and 36.

The Examiner has rejected claims 16 and 36 under 35 U.S.C. §102(b), as allegedly being anticipated by Gasprova et al., Chem Abstract 124: 55745. The Examiner alleges that the instantly claimed compounds read on the reference compounds where R is heteroaryl. Applicants respectfully traverse this rejection.

With respect to the Examiner's allegation that claims 16-21 are anticipated by Gasprova et al., compounds I, IV, VII-XII do not anticipate Applicants' compound because at the 4-position of the benzoxazine or benzothiazine ring, Applicants' compound contains a nitrogen, whereas the compounds I, VI, VII-XII contain a carbon substituted with an oxo group. Compound II is a monocyclic compound and thus does not anticipate Applicants' compound. Compound III and compound IV are bicyclic carbocyclic compounds comprised of a five-membered fused to a six-membered ring and as such do not anticipate Applicants' compound. Compound VI does not anticipate Applicants' compound because it is a tricyclic compound whereas Applicants' compound is bicyclic. Claim 16 has been amended to proviso out the following compounds: RN 172170-70-6, RN172170-68-2, RN172170-69-3, RN 172170-72-8, RN 172170-73-9. Therefore, Gasprova et al. does not anticipate Applicants' claims 16-21 as amended herein.

The Examiner has rejected claims 16 and 36 under 35 U.S.C. §102(b), as allegedly being anticipated by Kawashima et al. (WO 95/13269). The Examiner alleges that Kawashima et al. teaches the compounds and composition of the instant invention, specifically example 7 on page 20. Claim 16 has been amended to proviso out example 7 on page 20. Thus, Kawashima et al. does not anticipate Applicants' claims 16 and 36 as amended herein.

The Examiner has rejected claims 16 and 36 under 35 U.S.C. §102(b), as allegedly being anticipated by Kawashima et al. (WO 95/13267). The Examiner alleges that Kawashima teaches

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the compounds and composition of the instant invention. Applicants respectfully traverse this rejection.

Examples 1 through 10 of WO 95/13267, plus the compounds which can be prepared by the similar method as Example 1, do not anticipate Applicants' claims 16 and 36 because they are substituted at the 4-position of the benzothiazine ring. Applicants' compound is unsubstituted in this position. Applicants have amended claim 16 to proviso out Reference Examples 1-3. Thus, WO 95/13267 does not anticipate Applicants' claims 16 and 36 as amended herein.

The Examiner has rejected claims 16 and 36 under 35 U.S.C. §102(b), as allegedly being anticipated by Sakuta et al., Chem Abstract 119: 63033. Applicants have amended claim 16 to proviso out the compound having RN 108402-28-4. Thus, Sakuta et al. does not anticipate Applicants' claims 16 and 36 as amended herein.

The Examiner has rejected claim 16 under 35 U.S.C. §102(b), as allegedly being anticipated by McCarthy et al., Chem. Abstract 110:38945. The Examiner alleges that the instantly claimed compounds read on the reference compound. Applicants have amended claim 16 to proviso out the following compounds: RN 24545-07-1, RN 54874-84-9, RN 54874-85-0, RN 95476-30-5, 95476-37-2, RN 101884-21-3, RN 118265-38-6, RN 118265-39-7, RN 118265-40-0 and RN 118265-41-1. Thus, McCarthy et al., does not anticipate Applicants' claims 16 and 36 as amended herein.

The Examiner has rejected claims 16 and 36 under 35 U.S.C. §102(b), as allegedly being anticipated by Hamari et al., Chem Abstract 103:142032. The Examiner alleges that the instantly claimed compounds read on the reference compound. Applicants respectfully traverse this rejection.

With respect to the Examiner's allegation that claims 16 and 36 are anticipated by reference Hamari et al., Applicants point out that in RN 98448-65-8 and RN 98448-66-9 the nitrogen at the 4-position of the benzothiazine ring is substituted by an alkyl group, whereas in Applicants' compound the nitrogen is unsubstituted. Applicants have amended claim 16 to proviso out the following compounds: RN 54874-55-4, RN 95476-30-5, RN 95476-31-6, and RN 98448-63-6. Thus, Hamari et al. does not anticipate Applicants' claims 16 and 36 as amended herein.

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The Examiner has rejected claims 16 and 36 under 35 U.S.C. §102(b), as allegedly being anticipated by Maki et al. (U.S. Patent 4,490,292). The Examiner alleges that Maki et al. teaches the compounds and composition of the instant invention. Applicants respectfully traverse this rejection.

With respect to the Examiner's allegation that claims 16 and 36 are anticipated by reference Maki et al., examples 1 and 2 of Maki et al. are benzothiazepine compounds, not benzothiazines and thus do not anticipate Applicants' claims 16 and 36. Examples 4 and 6 of Maki et al. have a morpholino group at the 4-position of the benzoxazine ring whereas in Applicants' claim 16, the 4-position is unsubstituted. Example 7 of Maki et al. has a dimethylaminoethyl group at the 4-position of the benzoxazine ring whereas in Applicants' claim 16 the 4-position is unsubstituted. In RN 85809-67-2 and RN 30752-17-1 the nitrogen at the 3-position is substituted whereas in Applicants' compounds this position is unsubstituted.

Claim 16 has been amended to proviso out the compounds:

RN 54876-31-6P, RN 95476-31-6, RN 95476-11-2P,

2-(4-Chlorophenylmethylidene)-2H-1,4-benzothiazine-3(4H)-one (example 3, RN 54874-85-0),

2-(2,4-dichlorophenylmethylidene)-2H-1,4-benzothiazine-3(4H)-one (example 5, RN 54874-55-4), and

2-(4-methoxyphenyl)-2,3-dihydro-5-(2-dimethylaminoethyl)-1,5-benzothiazepine-3,4(5H)-dione hydrochloride (example 8, RN 95476-11-2).

The Examiner has rejected claims 16 and 36 under 35 U.S.C. §102(b), as allegedly being anticipated by Krapcho et al. (U.S. Patent 4,078,062). The Examiner alleges that the instantly claimed compounds read on the reference compound. Applicants respectfully traverse this rejection.

Examples 1, 2, 5, 7-9, 11-18, 20-23, 25-26 and 28-30 of Krapcho et al. do not anticipate Applicants' claims 16 and 36 because these compounds are substituted at the 4-position of the benzothiazine ring, whereas Applicants' compounds are unsubstituted at this position. Examples 6-13, 15-16, 21-23, 27 and 28 of Krapcho et al. do not anticipate Applicants' claims 16 and 36 because these compounds are substituted on the benzene ring of the benzothiazine core of the molecule, whereas Applicants' compounds the benzene ring is unsubstituted. Claim 16 has been

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amended to proviso out examples 3, 4, 19 and 24. Thus, Krapcho et al. does not anticipate claims 16 and 36 as amended herein.

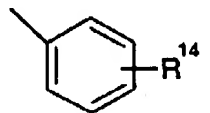
The Examiner has rejected claims 16 and 36 under 35 U.S.C. §102(b), as allegedly being anticipated by Anzai et al., Chem Abstract 82:140162. Applicants have amended claim 16 to exclude the compounds with the RN numbers 24545-07-1, 50393-32-3, 54874-53-2, 54874-54-3, 54874-55-4, 54874-62-3, 54874-84-9, 54874-85-0, 54913-29-0. Thus Anzai et al. does not anticipate claims 16 and 36 as amended herein.

The Examiner has rejected claims 16, 17 and 36 under 35 U.S.C. §102(b), as allegedly being anticipated by Krapcho et al., (J. Med. Chem., 1973). The Examiner alleges that the instantly claimed compounds read on the reference compound, see Table III, page 779.

Applicants respectfully traverse this rejection.

Formulas IIIb and IV, and the figures in Tables 1 and 2 of reference Krapcho et al., the nitrogen at the 4 position of the benzoxazine ring is substituted whereas in Applicants' claim 16 the nitrogen at the 4 position is unsubstituted. With respect to Formula II in Krapcho et al., this compound, as well as compounds a, c, e and h in Table III, are specifically excluded by the original proviso in Applicants' claim 16 which states:

when X is O and n is 0, R¹ is hydrogen or a substituted or unsubstituted aliphatic group and R is a substituted or unsubstituted aromatic or aralkyl group, *provided that R is not* thiophenyl, benzoxadiazolyl, 3-furanyl, 3-pyridinyl or



where R¹⁴ is H, CF₃, phenyl, OCH₃, -O-phenyl, NO₂ or -OC(O)CH₃...

Claim 16 has been amended to proviso out compounds b, d, f and g of Table III of Krapcho et al. Therefore, Krapcho et al., does not anticipate Applicants' claim 16 as amended herein.

Based upon the foregoing, the rejection of claims 16-26 and 36 under 35 U.S.C. §112, first paragraph, and 35 U.S.C. §102(b) is obviated and should be withdrawn.

The Examiner has rejected claims 16-26 under 35 U.S.C. §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention. The Examiner alleges that claim 16 is indefinite in that the metes and bounds of "a substituent" are unknown and that there is no definition for this term in the specification. In the Office Action mailed December 24, 2002, the Examiner acknowledged that there is, however, a definition of "suitable substituent" in the specification.

In the Reply mailed March 24, 2003, Applicants amended claim 16 to include the phrase "suitable substituents". It is Applicants' understanding, based upon the telephonic interview conducted January 20, 2004, that with this amendment the rejection of claims 16-26 under 35 U.S.C. §112, second paragraph, is obviated and will be withdrawn.

Based upon the foregoing, Applicants believe that claims 16-26 and 36 are in condition for allowance. Prompt and favorable action is earnestly solicited.

If the Examiner believes that a telephone conference would advance the condition of the instant application for allowance, Applicants invite the Examiner to call Applicants' agent at the number noted below.

Respectfully submitted,

Date: January 22, 2004

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